The Substance Abuse Prevention and Control (SAPC), a program within the Los Angeles County Department of Public Health (DPH) and Health Agency, will implement an initial benefit package of Substance Use Disorder (SUD) services within the initial twelve months of approval of its Drug Medi-Cal Organized Delivery System (DMC-ODS) implementation plan. The initial benefit package will include Opioid Treatment Program (OTP) level of care, as well as Medication-Assisted Treatment (MAT) services.

### Background:

OTPs provide opioid treatment for individuals using opioid agonist medications such as methadone or buprenorphine, but also address other SUDs and may offer other MAT in addition to these opioid agonist medications. MAT is the combination of addiction medications with behavioral therapies, such as counseling, to provide a comprehensive, biopsychosocial approach to the treatment of SUDs. There are currently several medications approved by the Food and Drug Administration (FDA) for the treatment of addiction in adults (see Table 1). In summary, while MAT is provided in OTPs, OTPs offer a broader range of services than just MAT, such as medical services, perinatal services, psychosocial services, etc.

As a level of care within the continuum of SUD care, medical necessity for OTP services can be determined by a Licensed Practitioner of the Healing Arts (LPHA<sup>1</sup>), including a Medical Director. In contrast, medical necessity for MAT services should be determined by physicians and/or prescribers operating within their scope of practice. However, similar to other health fields in which nurses and dental hygienists play a critical role in informing clients of available treatment options, other addiction health providers such as counselors and non-prescriber LPHAs still play an important role in identifying individuals who may benefit from MAT, discussing this treatment option with them, and referring them to health professionals who can determine if this is a medically necessary intervention. In order to achieve a state of the art SUD system of care, and maximize the evidence-based treatment options available to clients by offering MAT in conjunction with counseling and psychosocial interventions, SUD providers from across disciplines will need to work together to ensure familiarity with and access to MAT, both in OTP settings, as well as other settings. The passive or active discouragement of the use of FDAapproved addiction medications is contrary to the science of effective SUD treatment, and MAT should be discussed as a treatment option for all patients who express interest and for whom it may be appropriate and helpful.

Given that SUDs are chronic conditions, long-term maintenance treatment with MAT is a necessary and appropriate component of an effective treatment plan for many patients, similar to how long-term treatment with medications is oftentimes necessary for other chronic conditions. As such, the duration of MAT and OTP treatment, and the choice of medication, should be based on patient need and take into consideration the unique circumstances of the individual, the clinical judgment of the prescriber and benefits of MAT, as well as patient preference. Treatment with MAT and in the OTP setting should continue as long as medically necessary to reduce or eliminate the craving to use and misuse drugs. Discontinuation of maintenance treatment and

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<sup>&</sup>lt;sup>1</sup> A Licensed Practitioner of the Healing Arts is defined as one of the following professional categories: Physician (MD or DO), nurse practitioner, physician assistant, registered nurse, registered pharmacist, licensed clinical psychologist, licensed clinical social worker, licensed professional clinical counselor, licensed marriage and family therapist, or license-eligible practitioners working under the supervision of licensed clinicians.

MAT is a medical decision and should include consultation with the treatment provider's medical staff. Importantly, MAT should not be discontinued without the full cooperation of both the prescriber and the patient.

Services provided in an OTP level of care must occur in a Department of Health Care Services (DHCS) licensed OTP facility, and MAT is a service that can be provided in OTP settings and at all ASAM (American Society of Addiction Medicine) levels of care, aside from ASAM level 0.5, as well as in physical and mental health systems (excluding methadone for addiction treatment, which must occur in OTP settings).

The prescribing of MAT and provision of OTP services must be in compliance with all federal, state, and local laws and regulations. The following is a description of billable service components, staffing requirements, and service expectations for MAT and OTP benefits.

### **Medication-Assisted Treatment**

Research has demonstrated that for the treatment of addiction, a combination of medications and behavioral therapies is more successful than either intervention alone. As a result, when deemed clinically appropriate and when combined with psychosocial interventions, behavioral therapies, and necessary case management and care coordination, MAT is an evidence-based treatment that can improve outcomes and the likelihood of recovery. Subsequently, MAT should be provided in conjunction with counseling and other behavioral therapies, and needs to be part of a comprehensive, whole-person approach to the treatment of SUDs.

**Table 1: FDA-Approved Medications for Addiction** 

Opioid Use Disorder	Alcohol Use Disorder	Tobacco Use Disorder
Methadone	Naltrexone	
*Approved to treat individuals age 16 and	*Oral and long-acting injectable	Varenicline
older if federal prerequisites are met	formulations	
Buprenorphine	Disulfiram	
*Approved to treat individuals age 16 and	Distillani	Buproprion
older, when clinically appropriate		
Naltrexone		Nicotine replacement
*Oral and long-acting injectable	Acamprosate	therapy
formulations		therapy
Naloxone		
*Approved for opioid overdose prevention		

There are currently several FDA-approved medications for the treatment of various types of addiction (see Table 1). While methadone and buprenorphine are approved to treat individuals age 16 and older under certain conditions, current and emerging knowledge is that the routine use of MAT for adolescents is premature and requires further study. Other pharmacotherapies are used off-label for the treatment of addiction in adults and adolescents, but should be used cautiously and only on a case-by-case basis when deemed clinically appropriate by a licensed prescriber. The use and dosages of MAT should also be carefully considered in the treatment of elderly and adolescent populations, who oftentimes require unique treatment approaches given variable body composition and metabolism. While the provision of MAT does not require

preauthorization, MAT in the youth population under age 18 will require authorization by Quality Improvement / Utilization Management (QI/UM) staff at SAPC.

Medication-assisted treatment is available in various treatment settings and can be provided in OTP settings, at all ASAM levels of care aside from ASAM level 0.5, as well as in physical and mental health systems (excluding methadone for addiction treatment, which must occur in OTP settings). The administering and dispensing of MAT will vary depending on the setting in which the patient is receiving treatment for a substance use disorder.

- Primary care setting (non-Drug Medi-Cal)
  - O If a patient is receiving SUD treatment in a non-Drug-Medi-Cal (DMC) setting, such as a non-DMC primary care office, the prescribing, ordering, and monitoring of the MAT medication would occur during the office visit and the patient would fill the prescription at a pharmacy, which would be reimbursed for the medication and its dispensing.
- Drug Medi-Cal setting
  - Olients coming directly to a Drug Medi-Cal (DMC) outpatient program or an OTP may be prescribed MAT through a prescriber at the program, which is responsible for the prescribing, ordering, and monitoring of MAT. In the DMC outpatient setting, patients would fill the prescription at the pharmacy, while in the OTP setting, the dispensing and administration of MAT would occur at the OTP site. In the case of long-acting injectable naltrexone (aka: Vivitrol), medical providers may administer the drug in the office, which is termed a "physician administered drug." In these instances, the physician is reimbursed for the medication and the administration directly, and thus the program providing MAT is reimbursed for all components of MAT provision: ordering, prescribing, administering, and monitoring.

As such, MAT is available through DMC and also outside of DMC programs, and may be billed to DMC or fee-for-service (FFS) Medi-Cal as a pharmacy benefit. Reimbursement for medications is detailed in Table 2. Currently, certain MAT options –buprenorphine, long-acting injectable naltrexone, and acamprosate – require the submission of Treatment Authorization Request (TAR) to justify reimbursement for these medications through FFS Medi-Cal, though long-acting injectable naltrexone does not require a TAR when administered via DMC programs in counties that opt-in to the DMC-ODS waiver. When provided through FFS Medi-Cal, MAT must be provided from a Medi-Cal certified site. When MAT is provided through the DMC program, the licensed prescriber of the MAT must originate from a DMC certified site, though Field-Based Services for MAT provision is available when deemed medically necessary for individuals who are DMC-eligible.

**Table 2: Medication-Assisted Treatment Drug Reimbursement through Drug Medi-Cal** and the Medical System

Medication	Treatment Authorization Request (TAR) Required?	Availability
Methadone	No	Only in OTP setting
Buprenorphine	Yes (unless provided in OTP setting)	Pharmacy Benefit, OTP
Naltrexone tablets	No	Pharmacy Benefit, Outpatient Drug Free (ODF) DMC

		Benefit
Naltrexone long-acting	Yes (for FFS Medi-Cal)	Pharmacy Benefit, Physician
injection (aka: Vivitrol)	No (for DMC in DMC-ODS opt-in counties)	Administered Drug
Disulfiram	No	Pharmacy Benefit, OTP
Acamprosate	Yes	Pharmacy Benefit
Naloxone	No	Pharmacy Benefit, OTP

Given the biopsychosocial nature of addiction, all available clinically indicated psychosocial and pharmacological therapies such as MAT need to be discussed and offered as a concurrent treatment option for appropriate individuals with an alcohol and/or opioid related SUD condition at all levels of care. When MAT is part of the treatment plan, licensed prescribers operating within their scope of practice should assist the patient to collaborate in clinical decision-making, assuring that the patient is aware of all appropriate therapeutic alternatives. Informed consent for all pharmacotherapies must be obtained, including discussion about the advantages and disadvantages of MAT, taking into consideration the benefits, side effects, alternatives, cost, availability, and potential for diversion, among other factors.

Details regarding the availability, pharmacology, and appropriate prescribing of FDA-approved medications for addiction are beyond the scope of this document. However, MAT must be provided in accordance with an individualized treatment plan determined by a licensed prescriber, and should follow standards of practice, including the below resources from the ASAM and the Substance Abuse and Mental Health Services Administration (SAMHSA), respectively:

- The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use <a href="http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=16">http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf?sfvrsn=16</a>
- SAMHSA Medication for the Treatment of Alcohol Use Disorder: A Brief Guide <a href="http://store.samhsa.gov/shin/content/SMA15-4907/SMA15-4907.pdf">http://store.samhsa.gov/shin/content/SMA15-4907/SMA15-4907.pdf</a>

While there is not a widely agreed upon standard for drug testing in SUD treatment, it is often a useful tool to monitor engagement and provide an objective measure of treatment efficacy and progress to inform treatment decisions. The frequency of drug testing should be based on the patient's progress in treatment, and the frequency of testing should be higher during the initial phases of treatment when continued drug use has been identified to be more common. Additionally, drug testing is best when administered randomly as opposed to being scheduled, and the method of drug testing (e.g., urine, saliva) would ideally vary as well.

#### **Opioid Treatment Program**

OTPs constitute a level of care within the ASAM continuum and provide MAT and psychosocial services such as counseling for individuals diagnosed with opioid use disorders, as well as other SUDs and/or co-occurring physical and mental health conditions. Depending on the unique circumstances of each case, all patients who are diagnosed with an opioid use disorder may benefit from OTP services and should have access to this level of care.

The medications used to achieve treatment goals in OTP settings include methadone,

buprenorphine, and extended-release injectable naltrexone, which are all FDA-approved for use in the treatment of opioid use disorder. Other MAT options available in OTP settings include naloxone for opioid overdose prevention, and acamprosate and disulfiram for alcohol use disorder.

Persons treated in OTP settings must receive, at minimum, 50 minutes of counseling sessions with a therapist or counselor per calendar month, up to a maximum of 200 minutes. Additional services may be provided based on medical necessity.

The duration of OTP treatment and choice of medication should be based on patient need and take into consideration the unique situations of the individual, the clinical judgment of the prescriber and benefits of MAT, as well as patient preference. Given that SUDs are chronic conditions, long-term maintenance treatment with MAT in OTP settings is often a necessary and appropriate component of an effective treatment plan for many patients, similar to how long-term treatment with medications is oftentimes necessary for other chronic conditions. Discontinuation of MAT and treatment in the OTP setting is a medical decision and should include consultation with the treatment provider's medical staff. Importantly, MAT should not be discontinued without the full cooperation of both the prescriber and the patient.

Medically necessary OTP services should be provided in accordance with an individualized treatment plan determined by a licensed prescriber and approved and authorized according to all federal, state, and local laws and regulations. Care provided in OTP settings should follow standards of practice, including SAMHSA's Federal Guidelines for Opioid Treatment Programs (<a href="http://store.samhsa.gov/shin/content//PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf">http://store.samhsa.gov/shin/content//PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf</a>).

#### Service Components:

The components of OTP services include:

- Intake: The process of determining that a patient meets the medical necessity criteria, and then admitting a patient into a SUD treatment program. Intake includes the evaluation or analysis to determine whether or not an individual meets the current Diagnostic and Statistical Manual (DSM) of Mental Disorders criteria for an SUD diagnosis, and the assessment of treatment needs to provide medically necessary services using the SAPC-developed Full ASAM Assessment. Intake may include a physical examination and laboratory testing necessary for determining and providing appropriate SUD treatment.
- *Individual Counseling*: Contact between a registered/certified SUD counselor or LPHA and a patient that addresses psychosocial issues related to substance use using techniques such as Motivational Interviewing and Cognitive Behavioral Therapy. Services provided in-person, by telephone, or by telehealth qualify as Medi-Cal reimbursable units of service.
- Group Counseling: Face-to-face contacts between one or more certified SUD counselors or LPHAs, and two or more clients at the same time (with a maximum of 12 clients in the group), in which psychosocial issues related to substance use are addressed using techniques such as Motivational Interviewing and Cognitive Behavioral Therapy. Counseling and peersupport focus on the needs of the individuals served.
- Patient Education: Provide research-based education on addiction, treatment, recovery and associated health risks with the goal of minimizing the use of addictive substances, lowering the risk of dependence, and minimizing adverse consequences of substance use. Group

- counseling size parameters apply if patient education is conducted in a group setting.
- Medication Services: MAT will be discussed and offered as a concurrent treatment option for individuals with an alcohol- and/or opioid-related SUD condition and who are receiving services at this level of care. The prescription or administration of MAT, and the assessment of side effects and/or impact of these medications, should be conducted by staff lawfully authorized to provide such services within their scope of practice and licensure. Youth under age 18 are eligible for MAT on a case-by-case basis with parental consent and authorization from SAPC.
- Collateral Services: Sessions with a certified SUD counselor or LPHA and significant persons in the life of the patient that focus on the treatment needs of the patient in terms of supporting the achievement of the patient's treatment goals. Significant persons are individuals that have a personal, not official or professional, relationship with the patient. Sessions may occur via face-to-face encounters, telephone, or telehealth.
- Crisis Intervention Services: Contact between a certified SUD counselor or LPHA and a patient in crisis. Services shall focus on alleviating crisis problems. "Crisis" means an actual relapse or an unforeseen event or circumstance that presents to the patient an imminent threat of relapse, or a threat to physical and/or mental health and well-being. Crisis intervention services shall be limited to the stabilization of the patient's emergency situation, and should include appropriate linkage to services to ensure ongoing care following the crisis situation.
- Treatment Planning: The provider (certified SUD counselor or LPHA) shall prepare an individualized written treatment plan, based upon information obtained in the intake and assessment process. The treatment plan will be completed upon intake, reviewed at least every 30 days, and then updated every 90 days, unless there is a change in the patient's situation or a change in treatment modality that would require a new or revised treatment plan. The treatment plan shall include:
  - o A statement of problems to be addressed.
  - o Goals to be reached which address each problem.
  - o Action steps to be taken by the provider and/or patient to accomplish identified goals;
  - o Target dates for accomplishment of action steps and goals.
  - A description of services including the type of counseling to be provided and the frequency thereof.
  - Specific quantifiable goals and treatment objectives (e.g., SMART goals that are <u>Specific, Measurable, Attainable, Realistic, and Time-bound)</u> related the patient's SUD diagnosis and multidimensional assessment.
  - The proposed type(s) of interventions/modalities that includes frequency and duration of intervention(s).
  - o A treatment plan that is consistent with the qualifying diagnosis and must be signed by the patient and the LPHA or Medical Director.
- Medical Psychotherapy: Medically-oriented counseling consisting of a face-to-face discussion conducted by the Medical Director, or his/her designated licensed prescriber(s), of the OTP on a one-on-one basis with the patient. The focus of medical psychotherapy is to discuss all elements relevant to providing informed consent on medication options (risks and benefits of proposed intervention, alternatives, risks and benefits of foregoing any intervention, potential side effects, etc.), and other components of person-focused care that are necessary in order to provide a comprehensive range of medical and rehabilitative services.

• *Discharge Services*: The process to prepare the patient for referral into another level of care, post-treatment return or reentry into the community, and/or the linkage of the individual to essential community treatment, housing and human services. The discharge service process should be initiated from the onset of treatment services to ensure sufficient time to plan for the patient's transition to subsequent treatment or recovery support services.

## **Staffing for MAT and OTP Services**

Professional staff must be licensed, registered, certified, or recognized under California State scope of practice statutes. Professional staff shall provide services within their individual scope of practice and receive supervision required under their respective scope of practice laws. Certified SUD counselors must adhere to all requirements in the California Code of Regulations, Title 9, Chapter 8 and must be certified by one of the National Commission for Certifying Agencies (NCCA) accredited organizations recognized by DHCS: Addiction Counselor Certification Board of California (affiliated with California Association for Alcohol/Drug Educators (CAADE); California Association of DUI Treatment Programs (CADTP); California Consortium of Addiction Programs and Professionals (CCAPP). Services in the OTP setting may be provided by registered or certified SUD counselors or Licensed Practitioners of the Healing Arts (LPHA), depending on the nature of the service with respect to their scope of practice. A LPHA is defined as one of the following professional categories:

- Physician\* (MD or DO)
- Nurse Practitioner\* (NP)
- Physician Assistant\* (PA)
- Registered Nurse (RN)
- Registered Pharmacist (RP)
- Licensed Clinical Psychologist (LCP)
- Licensed Clinical Social Worker (LCSW)
- Licensed Professional Clinical Counselor (LPCC)
- Licensed Marriage and Family Therapist (LMFT)
- License-Eligible Practitioners working under the supervision of licensed clinicians

All potential licensed prescribers\* (MDs, DOs, NPs, PAs) in SAPC's network of care are urged to practice at the top of their licensed capability and to receive sufficient training with MAT to be able to prescribe these medications for addiction on either a routine or case-by-case basis in order to increase patient access to this core component of SUD treatment. Of note, only MDs and DOs are permitted to prescribe buprenorphine for addiction with required training, whereas other MAT options can be provided by the full spectrum of potential prescribers.

Non-professional staff including clerical, billing, and facility management support shall receive appropriate on-site orientation and training prior to performing assigned duties. Non-professional staff will be supervised by professional and/or administrative staff. Professional and non-professional staff are required to have appropriate experience and necessary training at the time of hiring.

## **Service Expectations for MAT and OTP Services**

• *Physical Examinations:* Appropriate medical evaluation must be performed prior to initiating MAT, including physical examinations when deemed necessary.

- Culturally Competent Services: Providers are required to provide culturally competent
  services that are culturally, linguistically, and developmentally appropriate in order to
  optimize treatment engagement. Providers must ensure that their policies, procedures, and
  practices are consistent with the principles outlined in the National Standards for Culturally
  and Linguistically Appropriate Services (CLAS) in Health and Health Care and are
  embedded into the organizational structure and day-to-day operations of the agency.
- Evidenced Based Practices (EBP): Providers will be expected to implement, at a minimum, the two EBPs of Motivational Interviewing (MI) and Cognitive Behavioral Therapy (CBT). Other EBPs include relapse prevention, trauma informed treatment, and psychoeducation.
- Case Management and Recovery Support Services: Providers will be expected to deliver a variety of case management and care coordination services including transitioning clients from one level of SUD care to another, and navigating the mental health, physical health, and social service delivery systems.
- Documentation: Services provided in the community, by telephone, or by telehealth require
  equivalent quality and comprehensiveness of documentation as in-person services provided
  within a certified facility. The SAPC will require that providers generate initial
  documentation based on the ASAM Criteria and that documentation provides justification for
  the care provided, including documentation of medical necessity. Documentation templates
  developed by SAPC shall be used for treatment plans, progress notes, and other
  documentation developed by the Quality Improvement/Utilization Management (QI/UM)
  Unit.
- Field-Based Services (FBS): Field-Based Services are specialty SUD services provided by registered/certified SUD counselors or LPHAs specifically trained to recognize and respond to the unique biopsychosocial needs of their clients. Field-Based Services are responsive and appropriate to the cultural, linguistic, and developmental needs of patients, and are supported by evidenced-based practices. Depending on the treatment situation, MAT may be prescribed (but not administered) via FBS. The services will be provided to adults and youth, as well as parents or guardians, as needed. Service locations include, but are not limited to, client's residence, recreational centers, sober living facilities, homeless encampments, and colocations in emergency departments, primary care, mental health, court, jail re-entry (not incustody), probation, and child protective services settings.

## Final Note:

SUD treatment should be delivered across a continuum of services that reflect the severity of the condition and the intensity of services required. One of the key goals of the SAPC is to ensure that clients receiving SUD services in Los Angeles County receive the right service, at the right time, for the right duration, in the right setting. While the levels of care are presented as discrete hierarchies, they should be viewed as points along a continuum of treatment services.